

Remarks

Claims 1-35 were pending. By way of this response, claims 1-4, 6-7, 9-10, and 12 have been amended, claims 5, 8, 11, and 13-35 have been cancelled without prejudice, and claims 36-44 have been added. Support for the amendments to the specification and the claims can be found in the application as originally filed, and no new matter has been added. Accordingly, claims 1-4, 6-7, 9-10, 12, and 36-44 are currently pending.

Claim Objections

Claim 1 has been objected to for the misspelling of involuntary. Claims 5, 10, and 11 have been objected to for including subject matter of non-elected inventions.

Claim 1 has been amended by removing the word "involuntary". Claims 5 and 11 have been cancelled, and claim 10 has been amended to be directed to the elected invention.

In view of the above, applicant submits the claim objections have been overcome.

Rejections Under 35 U.S.C. § 112, First Paragraph

Claims 1-12 have been rejected under 35 U.S.C. § 112, first paragraph.

As indicated above, independent claim 1 has been amended to indicate the method is for treating wrinkles, and claim 36 has

been added directed to a method of treating brow furrows. Applicant respectfully traverses the rejection as it relates to the amended and new claims. As acknowledged in the Office Action (page 3, last paragraph), methods for treating wrinkles and brow furrows are enabled by the specification of the above-identified patent application.

In view of the above, applicant submits the rejections under 35 U.S.C. § 112, first paragraph have been overcome.

Rejections Under 35 U.S.C. § 112, Second Paragraph

Claims 1-12 have been rejected under 35 U.S.C. § 112, second paragraph as allegedly indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

Claim 1, and new claim 36, include the amount of botulinum toxin administered to a patient, and the outcome of the treatment. Claim 4 has been amended to make the claim read more clearly. Claim 8 has been cancelled. Claim 10 has been amended by deleting the phrase "a variant thereof".

In view of the above, applicant submits that the present claims, and in particular claims 1-4, 6-7, 9-10, 12, and 36-44, satisfy the requirements of 35 U.S.C. § 112, second paragraph, and respectfully requests that the rejection of the present claims based on this statutory provision be withdrawn.

Rejections Under 35 U.S.C. § 103

Claims 1, 2, and 5-12 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Borodic (U.S. Patent No. 5,183,462) taken with Vadoud-Seyedi et al. (hereinafter Vadoud). Claims 3 and 4 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Borodic in view of Vadoud, and further in view of McCabe (U.S. Patent No. 5,525,510).

As indicated herein, claim 1, and the claims dependent therefrom, have been amended to reflect that the botulinum toxin is administered to treat wrinkles; and claims 36-44 have been added and are directed to the administration of a botulinum toxin to treat brow furrows. Applicant respectfully traverses the rejections as they relate to the amended claims.

Applicant submits that a person of ordinary skill in the art would not be motivated to combine the teachings of Borodic and Vadoud, and thus, the present claims are unobvious and patentable over the combination of Borodic and Vadoud under 35 U.S.C. § 103.

Vadoud discloses needleless injection of a botulinum toxin into the sole of a patient's foot to treat plantar hyperhydrosis. The soles of the feet were targeted because of the deeper location of the plantar nerves (see last paragraph). Vadoud discloses that needleless injection of botulinum toxin is not recommended for body regions containing superficial nerves or vessels, such as the palms of a patient's hand. Vadoud does not disclose, teach, or even suggest the use of a botulinum toxin to treat wrinkles or brow furrows.

Borodic discloses administration of a botulinum toxin by way of injection using a syringe with a needle. Borodic does not disclose, teach, or even suggest the use of a needleless syringe to deliver a botulinum toxin.

Wrinkles and brow furrows are relatively superficial cosmetic features formed by projections from muscles that are attached into the dermis. Body regions that are prone to wrinkles or brow furrows, such as facial regions, are densely innervated with blood vessels and nerves. In addition, the thickness of such body regions is relatively small, especially compared to the sole of a foot. Therefore, the blood vessels and nerves in such body regions are superficially located.

As indicated herein, Vadoud actually teaches away from using a needleless injection of botulinum toxin into body regions having superficial nerves and vessels. "As a general rule, references that teach away cannot serve to create a prima facie case of obviousness." (*McGinley v. Franklin Sports, Inc.* CAFC 8/21/01 citing *In re Gurley*, 31 USPQ2d 1131, (Fed. Cir. 1994)). Thus, applicant submits that a person of ordinary skill in the art would not be motivated to treat wrinkles or brow furrows with a botulinum toxin using a needleless syringe, and such a person would not be motivated to combine the teachings of Vadoud with Borodic.

In view of the above, applicant submits that the present claims, and in particular claims 1-2, 6-7, 9-10, 12, and 36-44, are unobvious from and patentable over Borodic in view of Vadoud under 35 U.S.C. § 103. In addition, applicant submits that

claims 3 and 4 are similarly unobvious from and patentable over the combination of Borodic in view of Vadoud and further in view of McCabe since a person of ordinary skill in the art would not be motivated to combine Borodic with Vadoud.

Each of the present dependent claims is separately patentable over the prior art. For example, none of the prior art disclose, teach, or even suggest the present methods including the additional feature or features recited in any of the present dependent claims. Therefore, applicant submits that each of the present claims is separately patentable over the prior art.

In conclusion, applicant has shown that the present claims satisfy the requirements of 35 U.S.C. § 112, and are not anticipated by and are unobvious from and patentable over the prior art under 35 U.S.C. §§ 102 and 103. Therefore, applicant submits that the present claims, that is claims 1-4, 6-7, 9-10, 12, and 36-44 are allowable. Therefore, applicant requests the Examiner to pass the above-identified application to issuance at an early date. Should any matters remain unresolved, the Examiner is requested to call (collect) applicant's attorney at the telephone number given below.

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Respectfully submitted,



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